



## Patient Information Sheet

### Vardenafil (marketed as Levitra)

This is a summary of the most important information about Levitra. For details, talk to your healthcare professional.

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**FDA ALERT [07/2005]:** A small number of men have lost eyesight in one eye some time after taking Levitra, Viagra, or Cialis. This type of vision loss is called non-arteritic anterior ischemic optic neuropathy (NAION). NAION causes a sudden loss of eyesight because blood flow is blocked to the optic nerve.

We do not know at this time if Levitra, Viagra, or Cialis cause NAION. NAION also happens in men who do not take these medicines. People who have a higher chance for NAION include those who:

- have heart disease
- are over 50 years old
- have diabetes
- have high blood pressure
- have high cholesterol
- smoke
- have certain eye problems

FDA has approved new labels for Levitra, Viagra, and Cialis to include information on possible eyesight loss (NAION).

**Stop using Levitra, Viagra, or Cialis if you have a loss in your eyesight. Get medical help right away.**

*This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.*

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#### What is Levitra?

Levitra is a medicine taken by mouth for the treatment of erectile dysfunction (ED) in men. ED is a condition where the penis does not harden and expand when a man is sexually excited, or when he cannot keep an erection. Levitra may help a man with ED get and keep an erection when he is sexually excited. Levitra must be used only under a doctor's care.

Levitra does not:

- cure ED
- increase a man's sexual desire
- protect a man or his partner from sexually transmitted diseases, including HIV. Speak to your healthcare professional about ways to guard against sexually transmitted diseases.
- serve as a male form of birth control

Levitra is only for men with ED. Levitra is not for women or children. Levitra must be used only under a healthcare professional's care.

#### Who Should Not Take Levitra?

Do not take Levitra if you:

- take any medicines called "nitrates"
- use recreational drugs called "poppers" like amyl nitrate and butyl nitrate
- have been told by your healthcare professional not to have sexual activity because you have health problems

#### What are The Risks?

*The following are the major possible risks and side effects of Levitra therapy. This list is not complete.*

Levitra can cause your blood pressure to drop suddenly to an unsafe level if it is taken with certain other medicines such as nitrates and alpha-blockers, and recreational drugs that contain nitrates called "poppers". A sudden drop in your blood pressure could cause you to become dizzy, faint, or have a heart attack or stroke.

Tell all your healthcare professionals that you take Levitra. If you need emergency medical care for a heart problem, it will be important for your healthcare professionals to know when you last took Levitra.

Levitra may uncommonly cause:

- an erection that won't go away (priapism)
- vision changes, such as seeing a blue tinge to objects or having difficulty telling the difference between the colors blue and green

Some common side effects with Levitra include:

- headache
- flushing
- stuffy or runny nose
- indigestion
- upset stomach
- dizziness

#### What Should I Tell My Healthcare Professional?

Tell your healthcare professional if you:

- have or had heart problems
- have low blood pressure or have high blood pressure that is not controlled

*Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570  
Druginfo@cder.fda.gov*





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- have had a stroke
- or any family members have a rare heart condition known as prolongation of the QT interval (long QT syndrome)
- have liver problems
- have kidney problems and require dialysis
- have ever had severe vision loss
- have retinitis pigmentosa, a rare genetic (runs in families) eye disease
- have stomach ulcers
- have a bleeding problem
- have a deformed penis shape or Peyronie's disease
- have had an erection that lasted more than 4 hours
- take any medicines called "alpha blockers" (alpha blockers are sometimes prescribed for prostate problems or high blood pressure)

- have blood cell problems, such as sickle cell anemia, multiple myeloma, or leukemia

#### Can Other Medicines or Food Affect Levitra?

Levitra and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

**Levitra FDA Approved 2003**  
**Patient Information Sheet Revised 07/2005**

